5. *Premarket Notification [510(k)] Summary*

K071218

Submitted By: Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220
Phone: (315) 685-4571
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Contact: John E. Sawyer, Vice-President, Quality Assurance & Regulatory Affairs

JUN 14 2007

Common Name: light, surgical, fiberoptic

Trade Name: ProXenon 350

Classification: Class II; 21 CFR § 878.4580, General & Plastic Surgery

Predicate Device: The Isolux Fiber Optic Surgical Headlight System with 510(k) number K991572

Description: The Welch Allyn ProXenon 350 Fiber Optic Surgical Illuminator is designed for use with fiber optic headlight systems. The ProXenon 350 Fiber Optic Surgical Illuminator uses a Welch Allyn high-intensity, narrow-beam, rugged xenon short arc lamp with a fixed internal reflector to produce a uniform profile beams. The Four Port Turret accepts Wolf, Storz, Olympus, and ACMI fiber optic cables. Each port is readily identified on the turret perimeter.

The ProXenon 350 system consists of 3 major components; a 300W Xenon light source, a fiber optic bundle, a headlight consisting of a luminaire (contains optics to focus and direct the illumination) and a headband.

The surgeon uses the headlight to provide auxiliary illumination when performing surgical procedures. The headlight is especially useful for illumination of deep body cavities since it provides shadow free illumination.

Intended Use: The ProXenon 350 Light Source is designed for use with fiber optic headlight systems. It will accept fiber optic light guides for Wolf, Storz, Olympus and ACMI instrumentation.

Accessory Headlight is a passive luminaire that is illuminated by fiber optic light and utilized to provide supplemental light for surgical and medical procedures.

OK PAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Welch Allyn, Inc.
% Mr. Chris Horacek
Vice President Chief
Compliance Officer
4341 State Street Road
P.O. Box 220
Skaneateles Falls, New York 13153-0220

JUN 14 2007

Re: K071218
Trade/Device Name: ProXenon 350
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FST
Dated: June 7, 2007
Received: June 12, 2007

Dear Mr. Horacek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

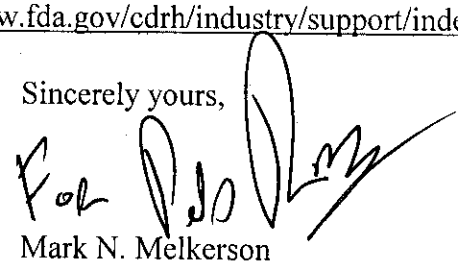
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. *Statement of Indications For Use*

510(k) Number (if known): _____

Device Name: ProXenon 350

Indications For Use: The ProXenon 350 Light Source is designed for use with fiber optic, headlight systems. It will accept fiber optic light guides for Wolf, Storz, Olympus and ACMI instrumentation.

Accessory Headlight is a passive luminaire that is illuminated by fiber optic light and utilized to provide supplemental light for surgical and medical procedures.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number L07128

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)